

Notice of Allowability

Application No.

10/032,482

Examiner

Sean E. Aeder, Ph.D.

Applicant(s)

COHEN ET AL.

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the amendment filed 12/22/05 and the Examiner's amendments.
2. ☒ The allowed claim(s) is/are 8-12, 17, 19-22 and 24-28.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☒ All b) ☐ Some* c) ☐ None of the:
 1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413),
Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____



GARY B. NICKOL, PH.D.
PRIMARY EXAMINER

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interviews with Allan Fanucci on March 3, 2006 at 5:30pm EST and March 21, 2006 at 3:00 EST.

The following claims were amended:

8. A synthetic peptide capable of eliciting antibodies to p53, which peptide is 7 to 30 amino acids in length of a variable region of an anti-p53 mAb and contains a sequence of a CDR of the heavy chain or light chain of the anti-p53 mAb, and salts thereof, wherein the sequence of the CDR is selected from the polypeptide sequences of mAb 240, mAb 246 and mAb 421.

11. A synthetic peptide according to claim 10, wherein the peptides are selected from the group consisting of peptides V-VII of the sequences:

Peptide V: Tyr-Tyr-Cys-Gln-His-Ile-Arg-Glu-Leu-Thr-Arg-Ser-Glu-Gly-Gly-Pro-Ser (SEQ ID NO:21),

Peptide VI: Gly-Val-Tyr-Tyr-Cys-Trp-Gln-Gly-Thr-His-Ser-Pro-Leu-Thr-Phe-Gly-

Art Unit: 1642

Ala-Gly-Thr-Lys (SEQ ID NO:22),

Peptide VII: Gly-Asp-Ile-Asn-Pro-Asn-Asn-Gly-Tyr-Thr-Ile-Tyr-Asn-Gln-Lys-Val-Lys-Gly-Lys-Ala (SEQ ID NO:23), and salts thereof.

19. The peptide of claim ~~189~~, wherein the peptide is selected from the group consisting of:

(i) peptides, herein designated Ia-Ib, containing the CDR2 and CDR3, respectively, of the heavy chain (240VH), and peptide Ic containing the CDR3 of the light chain (240VL), of the anti-p53 mAb 240, of the sequences: (Ia) Glu-Ile-Asp-Pro-Ser-Asp-Ser-Tyr-Thr-Asn-Tyr-Asn-Gln-Asn-Phe-Lys-Asp (SEQ ID NO:9), (Ib) Leu-Leu-Arg-Tyr-Phe-Ala-Met-Asp-Tyr (SEQ ID NO:10), or (Ic) Gln-His-Ile-Arg-Glu-Leu-Thr-Arg (SEQ ID NO:11);

(ii) peptides, herein designated IIa-IIb, containing the CDR2 and CDR3, respectively, of the heavy chain (246VH), and peptide 11c containing the CDR3 of the light chain (246VL), of the anti-p53 mAb 246, of the sequences: (IIa) Asp-Ile-Asn-Pro-Asn-Asn-Gly-Tyr-Thr-Ile-Tyr-Asn-Gln-Lys-Val-Lys-Gly (SEQ ID NO:12), (IIb) Gly-Gly-Gly-Leu-Lys-Gly-Tyr-Pro-Phe-Val-Tyr (SEQ ID NO:13), or (IIc) Gln-Gln-Arg-Ser-Ser-Phr-Pro-Phe-Thr (SEQ ID NO:14);

(iii) peptides, herein designated IVa-IVb, containing the CDR2 and CDR3, respectively, of the heavy chain (421 VH), and peptide IVc containing the DCR3 of the light chain (421 VL), of the anti-p53 mAb 421, of the sequences: (IVa) Trp-Ile-Asp-Pro-Glu-Asn-Gly-Asp-Thr-Glu-Tyr-Ala-Pro-Lys-Phe-Gln-Gly (SEQ ID NO:18), (IVb) Tyr-Gly-

Art Unit: 1642

Asp-Ala-Leu-Asp-Tyr (SEQ ID NO:19), or (IVc) Trp-Gln-Gly-Thr-His-Ser-Pro-Leu-Thr (SEQ ID NO:20); and salts thereof.

26. The pharmaceutical composition of claim 25, wherein the peptides are selected from the group consisting of peptides V-VII of the sequences:

Peptide V: Tyr-Tyr-Cys-Gln-His-Ile-Arg-Glu-Leu-Thr-Arg-Ser-Glu-Gly-Gly-Pro-Ser (SEQ ID NO:21),

Peptide VI: Gly-Val-Tyr-Tyr-Cys-Trp-Gln-Gly-Thr-His-Ser-Pro-Leu-Thr-Phe-Gly-Ala-Gly-Thr-Lys (SEQ ID NO:22),

Peptide VII: Gly-Asp-Ile-Asn-Pro-Asn-Asn-Gly-Tyr-Thr-Ile-Tyr-Asn-Gln-Lys-Val-Lys-Gly-Lys-Ala (SEQ ID NO:23), and salts thereof.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean E. Aeder, Ph.D. whose telephone number is 571-272-8787. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1642

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SEA

A handwritten signature in black ink, appearing to read "Gary B. Nickol". The signature is written in a cursive, flowing style.

**GARY B. NICKOL, PH.D.
PRIMARY EXAMINER**